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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,883	08/20/2001	Vaughn Vasil		4041

7590 12/12/2003

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,883

Applicant(s)

VASIL, VAUGHN

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12,14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12,14 and 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5, 7-9, 12, 17, 19-20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Giordano et al. (US Pat. 5,705,344). The reference discloses a screening assay for helicase inhibitors, wherein a mixture is formed of a first nucleic acid hybridized to an unlabeled second nucleic acid, a helicase, a nucleoside triphosphate, and a test agent. The first and second nucleic acids may both be DNA. The second nucleic acid is immobilized on a solid substrate, and the amount of label retained on the immobilized second nucleic acid is measured as an indication of helicase modulation (Claim 1). Helicases are enzymes that may function in various cellular functions, including DNA repair. The candidate helicase sample are typically cellular or nuclear extracts (Col. 7, lines 50-56). Detection may be carried out by coating the substrate with an antibody (claim 5 of reference).

3. Claims 1-2, 5, 7, 12, 14, 17, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (US Pat. 5,919,626). The reference discloses the attachment of nucleic acids to solid surfaces, wherein an unmodified nucleic acid molecule is coupled to a silane-coated solid phase. The unmodified nucleic acid molecules may be genomic DNA or cDNA. The solid support of the reference may be a microtiter plate. The method of the reference may also comprise the step of capturing from a solution at least one strand of a specific

Art Unit: 1641

polynucleotide analyte by hybridization to the immobilized nucleic acid molecule and detecting the captured analyte (claim 24 of reference). The analyte of the reference may also be protein.

4. Claims 1-2, 9, 12, 14, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (US Pat. 5,563,036). The reference discloses a method of screening for a compound comprising the steps of forming a mixture by combining a labeled protein and a nucleic acid conjugate, wherein the compound and a receptor are immobilized on a solid substrate, and said conjugate comprises a nucleotide sequence and a ligand specific for the receptor. The receptor then binds ligand, and in the absence of the compound, the labeled protein is bound to the nucleic acid conjugate. The presence or absence of the label on the protein on the substrate is then detected. The nucleic acid may be DNA or RNA. The solid phase of the reference may be a bead or microtiter plate. Exemplary ligand receptor pairs include antigen and antibody.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1641

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10-11 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giordano et al. (US Pat. 5,705,344) or Peterson et al. (US Pat. 5,563,036). The references teach screening assays, as previously discussed. However, the references do not teach DNA-PK or anti-DNA-PK antibody.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect DNA-PK and use anti-DNA-PK antibodies for this purpose because the selection of the analyte of interest merely represents an optimization of the assay protocol. Depending on the analyte of interest chosen, one of skill in the art would have known the appropriate antibody to use. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claims 4, 6, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giordano et al. (US Pat. 5,705,344), Shi et al. (US Pat. 5,919,626), or Peterson et al. (US Pat. 5,563,036) in view of Yamane (US Pat. 5,741,638).

Giordano et al., Shi et al., and Peterson et al. teach detection methods, as previously discussed. However, the references do not teach the use of damaged or UV-irradiated DNA.

Yamane teaches a microtiter well for detecting a nucleic acid. According to the reference, a single stranded nucleic acid that is specifically hybridizable with a target nucleic acid is immobilized on a microtiter well. Detection of the target analyte occurs after it contacts the immobilized single stranded nucleic acid. The immobilized nucleic acid may be DNA, and the DNA may be irradiated with UV to achieve immobilization (Example 4). When the label

Art Unit: 1641

used for detection is indirectly detectable, detection of target analyte may be carried out by using an acceptor (such as via the use of an antibody).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use damaged DNA as taught by Yamane with the methods of Giordano et al., Shi et al., or Peterson et al. because Peterson et al. state that any nucleic acid or analog may be used as long as sequence specific binding is still possible. The DNA may also be of any length. As such, one would have had a reasonable expectation of success is using damaged DNA with the methods of Giordano et al., Shi et al., or Peterson et al.

Response to Arguments

9. Applicant's arguments filed 9/3/03 have been fully considered and are persuasive to overcome Crute, Yamane, and Mitsuhashi as 102 references, but they are not persuasive to overcome the other pending rejections.

10. Applicant argues that Giordano involves the indirect detection of helicase activity through the detection of nucleic acid retained on the solid support. The examiner agrees with this assertion; however, such an arrangement has not been excluded by the present claims. The claims recite that the protein is detected while DNA substrate is bound to the solid support. In Giordano, the nucleic substrate is bound to the solid support, while protein is indirectly detected. The claims in no way require direct detection of the protein. In addition, applicant's arguments with respect to the 103 rejection are based on the premise that since helicase is not bound to the support, it cannot be detected with antibody; however, indirect detection can and does occur by contacting the substrate with antibody.

Art Unit: 1641

11. Applicant argues that Shi does not anticipate the claims because the reference only applies to polynucleotide analytes; however, the reference specifically states that the invention of the reference is useful in assays involving nucleic acids, as well as proteins. As such, the reference contemplates use of the immobilized oligonucleotides to bind protein as well and nucleic acid analytes.

Conclusion

Claims 1-2, 4-12, 14, and 16-23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-5207.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/10/03